EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OSTEOPLASTICS, LLC, Plaintiff, v. CONFORMIS, INC., Defendant.	C.A. No. 20-405-MN
OSTEOPLASTICS, LLC, Plaintiff, v. DEPUY SYNTHES, INC., DEPUY SYNTHES PRODUCTS, INC., MEDICAL DEVICE BUSINESS SERVICES, INC., AND SYNTHES, INC. Defendants.	C.A. No. 20-406-MN
OSTEOPLASTICS, LLC, Plaintiff, v. ZIMMER BIOMET HOLDINGS, INC. AND ZIMMER, INC. Defendants.	C.A. No. 20-407-MN

PLAINTIFF'S BRIEF IN OPPOSITION
TO DEFENDANTS' MOTION TO DISMISS

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I. INTRODUCTION

At the time of Osteoplastics' inventions, researchers had been working for at least a decade on computer-based approaches for designing custom medical devices. Some of the more advanced approaches at that time used image data of a patient's anatomy and attempted to create or modify a computer representation of healthy anatomy to determine the medical device shape for a specific patient. Defendants describe several examples of these computer-based methods, but leave out the fact they all suffered from serious shortcomings and could not reliably create a medical device that precisely fit patients' anatomy.

These shortcomings are what drove a distinguished group of individuals affiliated with Case Western Reserve University ("CWRU") to invent the patented technology in the late 1990s. The inventors include the former Chairman of the Department of Neurological Surgery at CWRU Medical School and University Hospitals of Cleveland, Dr. Robert Ratcheson, and Dr. David Dean, an expert in regenerative medicine.[1] The patented inventions improved on existing approaches with specific techniques claimed in the seven asserted patents.[2] Because the claimed techniques address and improve upon existing computer-based approaches, they are neither abstract nor ineligible subject matter under well-established precedent.

Defendants' motion ignores most of the claims in the asserted patents (addressing only one of them), ignores the actual claim language that describes specific improvements over existing computer-based approaches, and ignores the nearly 50 figures and over 40 columns of description of the inventions. Instead, Defendants oversimplify the claims to strip them of all

[1] CWRU later assigned its rights in the asserted patents to the inventors' company, Plaintiff Osteoplastics, LLC.

[2] The asserted patents include Patent No. 8,781,557, No. 9,929,920, No. 9,330,206, No. 9,626,756, No. 9,672,617, No. 9,672,302, and No. 9,275,191. These patents are referenced herein by their last three digits.

meaning and rely on vague characterizations about their "basic process" or "basic steps." Defendants take this approach to an extreme when they contend (at 1) that the claims "attempt to cover a physician who sits down at any computer terminal, looks at any 3D image of defective bone, places over it any image of intact bone, and tinkers with that shape using his or her brain and the computer." This level of "analysis" falls well short of the rigor required to invalidate every claim in the seven asserted Osteoplastics patents—claims that the patent office issued over prior computer-based methods and found to claim eligible subject matter under § 101. The Federal Circuit has cautioned against looking at the claims generally and failing to account for their specific, concrete requirements as Defendants do here.

Defendants are also wrong that the claims lack an inventive concept under the second step of the § 101 inquiry. The claims each recite specific, narrowly-drawn steps and techniques for designing and fabricating medical devices. They do not cover conventional, well-understood techniques for computer-based medical device design or preclude them. They also do not preclude the many other computer-based methods that attempted (but failed) to create suitable custom devices. These methods were available to Defendants if they had chosen to use them.

As for Defendants' infringement arguments, the Amended Complaint and attached claim charts contain detailed factual allegations that provide Defendants fair notice of the activities accused of infringement under § 271(a) and § 271(g). Likewise, Osteoplastics' willful infringement allegations exceed that required to satisfy the notice pleading standard in patent cases. Defendants' motion effectively asks the Court to create a new and heightened pleading standard that requires plaintiffs to prove their case at the pleading stage. The Court has declined this approach in the past and Osteoplastics respectfully requests the Court do so here.

II. NATURE AND STAGE OF PROCEEDINGS

On April 2, 2020, Osteoplastics filed Amended Complaints against the Defendants alleging infringement of seven patents. Osteoplastics filed these Complaints shortly after it resolved another patent infringement litigation in the District of Colorado filed in 2018, which involved many of the asserted patents. The defendants in that case (3D Systems Corporation, 3D Systems, Inc., and Medical Modeling, Inc., collectively, "3DS") agreed to a royalty on the methods accused of infringement. At the time of the agreement, the parties had briefed their claim construction disputes, which involved ten claim terms including eight referenced in claim 1 of the '206 patent. The Colorado court had not yet heard argument when the case was resolved and did not construe any of the disputed terms. Nevertheless, the claim construction briefing and evidence is publicly available, which includes a declaration from an expert in the field that addresses the meaning of several terms raised in Defendants' motion.[3]

III. SUMMARY OF THE ARGUMENT

1. The asserted patents claim patentable subject matter under step one of the *Alice* framework because they are directed to improvements over existing computer-based methods of designing custom medical devices. Defendants' motion improperly focuses on one claim from the seven patents and then glosses over the actual claim language that sets forth specific techniques demonstrating the claims are not abstract. The Osteoplastics claims are similar to other claims that the Federal Circuit has found patent-eligible under step one of *Alice*.

2. Osteoplastics' patents claim an inventive concept under step two of *Alice*. They capture significant improvements in the quality of custom medical devices as well as surgical

[3] Attached as Exhibit 1 is the Declaration of Dr. Milan Sonka that was filed in support of Osteoplastics' responsive claim construction brief in the Colorado action.

outcomes. Moreover, Defendants' discussion of several prior art methods that fall outside the scope of Osteoplastics' claims further shows there are no legitimate concerns of preemption.

3. The allegations and attached claim charts in Osteoplastics' Amended Complaints are more than sufficient to state a claim for infringement under § 271(g). Osteoplastics' infringement allegations identify the patented methods used in the manufacture of Defendants' infringing products. Nothing more is required to show infringement under § 271(g).

4. Osteoplastics' Amended Complaint against the DePuy Defendants includes sufficient allegations of patent infringement and complies with Rule 8. The Amended Complaint includes infringement claim charts that explain how each DePuy Defendant performs each step of the claims. Moreover, in pre-suit communications between the parties, DePuy refused to provide Osteoplastics with information relating to their infringing activities. Osteoplastics' filing—based on publicly-available information and relying on the *Hoffman-La Roche* line of cases—meets the pleading requirements. Osteoplastics' willful infringement claims are also sufficient because they allege pre-suit knowledge and infringement of three patents.[4]

IV. STATEMENT OF FACTS

A. At the Time of the Invention, There Were Significant Shortcomings with Computer-Based Methods of Designing Custom Medical Devices.

Before researchers began designing custom medical devices, the standard of care was to use mass-produced "shapes" chosen based on external measurements of the patient's anatomy. ('557 Patent at 4:21-23.)[5] In most cases, the surgeon had to remove portions of the patient's

[4] Osteoplastics does not oppose the dismissal of MDBS from the -406 action and will accept the representations that it has no regular and established place of business in this District.

[5] Unless otherwise indicated, all patent citations are to the '557 patent. The specifications of the asserted patents are identical, except that the '557 patent and its continuations disclose additional embodiments of the patented technology (described, e.g., in Figs. 45-49 and columns 7 and 36-44 of the '557 specification).

bony anatomy during the surgical procedure to obtain the proper fit with the device. (4:23-25.) As a result, these off-the-shelf medical devices caused longer surgeries, introduced complications, and lengthened patient recovery times. (4:44-50.)

The medical field was well aware of the problems with mass-produced, off-the-shelf devices. (4:32-39.) By the time of Osteoplastics' invention, numerous researchers had been working for at least a decade on ways to create custom medical devices that achieved better patient outcomes. Many of these methods focused on the use of computer-readable image data from individual patients (such as CT scans) and computer-aided design (CAD) to create the shape of the patient's medical device. The Background Section of the Osteoplastics patents references several of these approaches. (*E.g.*, 1:29-35.) Defendants also highlight some of them in their brief. For example, the Reuben reference discloses the use of patients' anatomical data in combination with "conventional steps using a commercially available CAD CAM system" to create prostheses. (*E.g.*, Defs' Ex. 1 ('565 patent), at 2:62-68.) Similar methods are disclosed in White (Pat. No. 4,436,684, Ex. 2) and Swaelens (Pat. No. 5,768,134, Ex. 3). These references disclose methods that include "manipulating [a] graphic tablet instrument" to manually create, translate, or delete components of a 3D medical device design. (*E.g.*, '684 at 17:3-10.) Other methods involved adding "artificial functional element[s]" to a 3D image of patient anatomy to build a device from scratch based on operator input. (*E.g.*, '134 at 4:20-34.)

Some prior art methods did not build devices "from scratch," but instead used static three-dimensional images as an aid for medical device designs. For example, D'Urso (Pat. No. 5,741,215, Defs' Ex. 2) and Ahrens (EP0255797) disclose the use of static mirror images of healthy portions of patient anatomy to create prostheses. In these methods, an operator could create the medical device shape by combining a mirror image with an image of a defect in the

anatomy, then "nullifying" (or subtracting) the existing anatomy to obtain an image "in the region of the defect." (*E.g.*, '215 at 8:7-23; *see also* Defs' Ex. 4 at 6 (Applicant's remarks on Ahrens during prosecution).) Other references, such as Delp, disclose overlaying pre-determined shapes of cutting jigs or "sizing templates" on patient images to guide surgeons in modifying and/or cutting away portions of the existing anatomy. (*See* Defs' Ex. 3 at 9 (Applicant's remarks on Delp during prosecution).)

All of these computer-based methods suffered from disadvantages that limited their usefulness. (*E.g.*, 1:19-4:56.) In general, prior art methods of "tinkering" with medical device shapes (as Defendants would put it) did not ensure that the custom medical device was of correct size and shape to fit to the existing anatomy. If an implant did not fit well enough, the patient could experience complications such as pain, atrophy, mechanical failure of the implant or the surrounding tissue, or rejection of the implant. (4:29-53.)

B. The Inventors Developed Novel Techniques for Designing Medical Devices that Overcame the Problems with Existing Methods.

Osteoplastics' inventions overcame these problems and provided a significant advance over existing computer-based methods of designing and fabricating custom devices. (*E.g.*, 1:19-7:61.) The claimed methods involved obtaining computer-readable image data of a patient. Notably, as shown in Fig. 1A below, the 3D representation of the patient anatomy from the image data includes a portion 18 with a defect and a portion 20 without a defect. (10:45-52.)

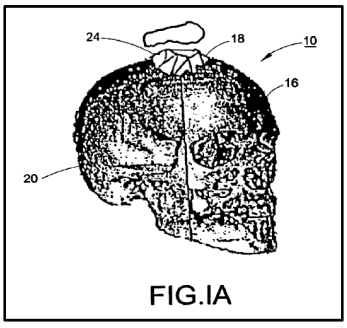
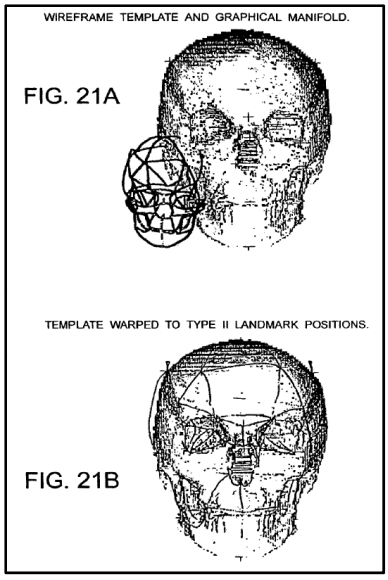


FIG.IA

The claims describe various embodiments with various techniques to design the shape of the medical device. These steps can include, for example, the identification of anatomical landmarks in the patient image that serve as reference points for the design process. (3:31-45, 20:29-33, 29:25-46, Fig. 19B.) The methods can also include the step of "superimposing" a deformable template onto the representation of the patient anatomy. To "superimpose" the patient's image data and the template data, the computer correlates the homologous anatomical features of the template and the representation of the target tissue. The template is a three-dimensional shape that represents a normative (e.g., non-distorted) shape of the patient anatomy. (10:45-54.) The patents explain that the shape of the template can be based on averaged data, mirror image data, standard data, or data from a relative. (3:52-55, 5:25-27, 42:7-9.) This use of a template is an improvement over "conventional" prior art methods for designing medical devices "from scratch" or methods involving manual modification of 3D images.

Using the identified anatomical landmarks on the template and the representation of the patient's tissue, the computerized methods include "deforming" the template. "Deforming" changes the shape of the template in three dimensions relative to the 3D representation of the patient anatomy so that the anatomical features of the template match the corresponding anatomical features of the representation of the patient's tissue and maintain the homology between those anatomical features. (*E.g.*, Figs. 21A-21B.) The "superimposing" and "deforming" steps improve on prior art methods that used static shape data (e.g., mirror images or "sizing templates") to define the shape of a device, without modifying the contours of the shape to match the existing anatomy.



After the template is deformed (e.g., Fig. 2, step G), it can be used to determine a medical device shape (e.g., Step I). In the case of an implant that replaces missing or defective bony structure, the medical device can be fabricated and then placed in the patient's anatomy (e.g., Step J). By "deforming" the template as claimed, the custom medical device achieved a precise fit that greatly improves patient outcomes.

Before issuing the claims of the asserted patents, the patent office reviewed numerous existing computer-based approaches for designing custom medical devices. The patent office also reviewed many of the claims and found the subject matter patent eligible under the *Alice* framework. (Ex. 4 ('206 File History Excerpts); Ex. 5 ('920 File History Excerpts); Ex. 6 ('302 File History Excerpts); Ex. 7 ('617 File History Excerpts).)

V. LEGAL STANDARDS

The pleadings in a patent case are governed by Rule 8, which requires only "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). To survive a motion to dismiss under Rule 12(b)(6), a complaint need only "state a claim to relief that is plausible on its face" and plead content "that allows the court to draw the

reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

In evaluating a motion to dismiss, the Court must "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009) (quoting *Phillips v. County of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008)). For a complaint alleging infringement and attaching the patents-in-suit, the "specification's statements about the purported invention" must also be accepted as true, and courts are "not free to accept [the] [d]efendant's contrary attorney argument." *MAZ Encryption Techs. LLC v. Blackberry Corp.*, C.A. No. 13-304-LPS, 2016 U.S. Dist. LEXIS 134000, at *15 (D. Del. Sept. 29, 2016).

Patent eligibility under 35 U.S.C. § 101 is an issue of law that may involve "underlying issues of fact." *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1365 (Fed. Cir. 2018). Where, as here, a motion to dismiss asserts the affirmative defense of patent invalidity under § 101, "dismissal is permitted only if the well-pleaded factual allegations in the Complaint, construed in the light most favorable to the plaintiff, suffice to establish the defense." *Kaavo Inc. v. Amazon.com Inc.*, C.A. No. 15-638-LPS-CJB, 2016 U.S. Dist. LEXIS 152336, at *6 (D. Del. Nov. 3, 2016); *see also Victaulic Co. v. Tieman*, 499 F.3d 227, 234 (3d Cir. 2007). "Rarely can a patent infringement suit be dismissed at the pleading stage for lack of patentable subject matter." *Bristol-Myers Squibb Co. v. Merck & Co.*, C.A. No. 15-560-GMS, 2016 U.S. Dist. LEXIS 34292, at *7 n.1 (D. Del. Mar. 17, 2016) (emphasizing issued patent "entitled to a presumption of validity under 35 U.S.C. § 282").

VI. THE ASSERTED PATENTS ARE DIRECTED TO ELIGIBLE SUBJECT MATTER UNDER § 101.

Under the first step of the § 101 framework, the Court must determine whether the claims are "directed to" ineligible subject matter, such as "abstract ideas" (the only ineligible subject matter Defendants allege here). *Alice Corp. Pty. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2355 (2014). This inquiry "cannot simply ask whether the claims involve a patent-ineligible concept, because essentially every routinely patent-eligible claim involving physical products and actions involves a law of nature and/or natural phenomenon . . . ." *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1335 (Fed. Cir. 2016); *see also Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293 (2012) ("[A]ll inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas."). "Rather, the 'directed to' inquiry applies a stage-one filter to claims, considered in light of the specification, based on whether 'their character as a whole is directed to excluded subject matter.'" *Enfish*, 822 F.3d at 1335 (quoting *Internet Patents Corp. v. Active Network, Inc.*, 790 F.3d 1343, 1346 (Fed. Cir. 2015)). "[T]he specification [is] helpful in illuminating what a claim is 'directed to.'" *Chamberlain Grp., Inc. v. Techtronic Indus. Co.*, 935 F.3d 1341, 1346 (Fed. Cir. 2019) (citation omitted).

"If the claims are directed to a patent-eligible concept, the claims satisfy § 101 and we need not proceed to the second step." *Core Wireless Licensing S.A.R.L. v. LG Elecs., Inc.*, 880 F.3d 1356, 1361 (Fed. Cir. 2018). But if analysis under the second step is necessary, the Court "examine[s] the elements of the claim to determine whether it contains an inventive concept sufficient to transform the claimed abstract idea into a patent-eligible application." *Alice*, 134 S. Ct. at 2357 (internal citation omitted). "The 'inventive concept' may arise in one or more of the individual claim limitations or in the ordered combination of the limitations." *BASCOM Global Internet Servs., Inc. v. AT&T Mobility LLC*, 827 F.3d 1341, 1349 (Fed. Cir. 2016).

A. The Osteoplastics Patents Claim Specific Improvements Over Existing Computer-Based Methods of Design and Fabrication.

When analyzing computer-based inventions, such as those here, claimed subject matter is patentable where it focuses on a "specific asserted improvement in computer capabilities" instead of on "a process that qualifies as an 'abstract idea' for which computers are invoked merely as a tool." *Finjan, Inc. v. Blue Coat Sys., Inc.*, 879 F.3d 1299, 1303 (Fed. Cir. 2018); *see also Uniloc USA, Inc. v. LG Elec. USA, Inc.*, 957 F.3d 1303, 1307 (Fed. Cir. 2020) ("We have routinely held software claims patent eligible under *Alice* step one when they are directed to improvements to the functionality of a computer or network platform itself.").

The existing computer-based methods at the time of the invention failed to provide custom medical devices with a precise fit to the existing patient anatomy. For example, "conventional" design methods that required humans to determine the device shape manually (e.g., "from scratch") with the aid of a computer program were unlikely to produce a device with the proper shape. Similarly, medical devices produced by simply using pre-determined shapes (e.g. mirror images) also failed to match a patient's unique anatomical contours.

The Osteoplastics patents improved on these approaches by using novel computer-based techniques to design and fabricate a medical device that precisely fits the existing anatomy and "requires only placement and minimal fixation by the attending clinician." (*E.g.*, 4:26-29.) Claim 1 of the '206 patent, which is the "representative" claim addressed in Defendants' motion, provides an example of a method with these improved techniques:

> A computer implemented method of obtaining data for determining a 3-dimensional shape of a medical device, the method comprising:
>
> (a) obtaining computer readable image data of a target tissue wherein the target tissue comprises two portions, a portion with a defect and a portion without a defect;

(b) rendering from the image data a computer-generated 3-dimensional representation of the target tissue;

(c) superimposing a three-dimensional template onto the 3-dimensional representation, wherein the three-dimensional template represents a normative shape of an anatomical surface of the target tissue; and

(d) deforming the three-dimensional template to the computer-generated 3-dimensional representation to determine the 3-dimensional shape of the medical device.

The computer-implemented method of claim 1 of the '206 patent first recites the step of obtaining computer readable image data of target tissue. The claim, however, requires that the data comprises two portions—a portion that includes the patient's defect and a portion of the patient's anatomy without a defect. The claim then recites the step of rendering a computer-generated 3-dimensional representation of the target tissue.

Next, the claim recites to the step of "superimposing a three-dimensional template onto the 3-dimensional representation." As the claim indicates, the three-dimensional template represents a "normative" shape of an anatomical surface of the target tissue. In the visual sense, the term "superimposing" generally means to place one thing over another. But in the context of the claim language, which is directed to a computer-implemented method, this visual definition is nonsensical and does not reflect the meaning of the term because both the patient image and template are computer data. (*E.g.*, 3:38-42, 10:65-67, 20:55-58, 22:28-38, 23:64-67; *see also* Ex. 1 ¶ 75.) To "superimpose" the patient's image data and the template data, the computer correlates the homologous anatomical features of the template and the representation of the target tissue. (*E.g.*, 2:46-3:7, 6:39-44, 6:64-7:3, 29:25-46; *see also* Ex. 1 ¶ 76-78.) While the computer may also display these images on a screen and the user may be able to interact with them, the "superimposing" of the data is performed by the computer.

The patent specifications confirms this application of the "superimposing" term. (*E.g.*, 2:46-3:7, 3:38-42, 6:39-44, 6:64-7:3, 10:65-67, 20:55-58, 22:28-38, 23:64-67, 29:25-46; *see also* Ex. 1 ¶¶ 76-78.) Several examples refer to "superimposing" where the anatomical features of the template correlate with those of the representation of the patient's target tissue. For example, the specification describes how "superimposition of the . . . deformable wireframe template [begins] with the identification of Type II landmarks" and that "the ridge curve and geodesic template wireframe is warped to the surface's Type II landmarks." (*E.g.*, 3:38-42.) It also discloses superimposing a wireframe template with landmarks on a "graphical manifold." (*E.g.*, 22:28-38, Figs. 21A-21B, 23:64-67, *see also* 3:38-42, 10:65-67, 20:55-58.) The specification also confirms that the template is superimposed based on homologous anatomical features. (*E.g.*, 2:46-3:7, 5:47-49, 5:56-64, 6:39-44, 6:64-7:3, 10:45-47, 23:64-67, 29:25-46, 41:60-63, 42:4-6; *see also* Ex. 1 ¶¶ 78, 83.) For example, it describes the "initially manual superimposition of a . . . deformable template to the perspectively rendered surface of interest at the Type II landmarks" in which a "superimposed ridge curve-based deformable template defines a homology mapped parametric surface." (*E.g.*, 2:46-3:7, 29:25-46, *see also* 6:64-7:3.) In addition, some embodiments disclose that "[t]he template establishes the homology for these three types of surface matching (i.e., mirroring, one-to-one fit, averaging)." (*E.g.*, 6:39-44.)

Defendants fixate on the limited "manual" aspects of these disclosed embodiments, wrongly arguing that a human could perform the claimed "superimposing" steps. (*E.g.*, Br. at 17.) Although most software allows human interaction, the specification repeatedly discloses that these embodiments of the invention use "semi-automatic" or "unsupervised" algorithms to perform the claimed "superimposing" step. (*E.g.*, 6:6-20, 6:45-53, 29:25-46.). Defendants also

fail to acknowledge that the "superimposing" step requires a computer capable of running the necessary specialized algorithms. (*E.g.*, 2:46-3:7, 6:64-7:3, 29:25-46; *see also* Ex. 1 ¶¶ 78, 83.)

Several claims, including claim 1 of the '206 patent, also recite the step of "deforming" a template to determine the shape of the implant or medical device. Some claims further specify that the template is deformed to "match the anatomical landmarks" on the representation of the patient's image. (*E.g.*, '920 claim 1, '302 claim 1.) In the claims, "deforming" requires the shape of the template be changed in three dimensions so that the anatomical features of the template match the corresponding anatomical features of the representation of the patient's tissue and, importantly, maintain the homology between those anatomical features. (*E.g.*, 2:46-3:7, 3:38-42, 6:39-44, 29:25-46; *see also* Ex. 1 ¶ 87-88.)

The specification confirms the meaning of "deforming" in the claims. (*E.g.*, 2:46-3:7, 3:38-42, 6:39-44, 29:25-46; *see also* Ex. 1 ¶¶ 88-90.) For example, the specification describes embodiments where "[o]nce the template is warped, points on the template are mapped, in a step H, to points on the external surface of the normative shape of the bone of interest 16." (*E.g.*, 10:65-67, *see also* 20:55-58.) The specification discloses deforming a three-dimensional wireframe template to corresponding landmarks on a three-dimensional "graphical manifold" representing patient tissue. (*E.g.*, 22:28-38, Figs. 2, 21A-21B; 23:64-67.) The specification further confirms that the deforming step is carried out using complex algorithms interacting with three-dimensional objects (e.g., wireframe and ridge curve-based templates). (2:46-3:7, 3:38-42, 6:39-44, 10:58-67, 20:55-58, 22:28-38, 23:64-67, 29:25-46, Figs. 21A-21B; Ex. 1 ¶¶ 88-90.) For example, to fit a wireframe or ridge curve-based template to a surface as described in the described embodiments, it is necessary to change the shape of the template in three dimensions. (2:46-3:7, 6:39-44, 10:58-65, 29:25-46; Ex. 1 ¶ 90.) The shape of the template may be changed

using techniques such as, e.g., "warping" or "a best fit process. (*E.g.*, 10:45-49, *see also* 43:5-7.) Moreover, the specification confirms that the deforming process maintains homology between the anatomical features: "[t]he template establishes the homology for . . . surface matching." (6:39-44; *see also* Ex. 1 ¶¶ 84-85.)

B. Defendants Improperly Oversimplify the Claims By Generalizing Them and Eliminating Their Specific Requirements.

Because the Osteoplastics claims set forth tangible, concrete steps that improved on existing computer-based methods, Defendants turn to generalizations of the claims to give the appearance of an abstract idea. This effort to strip the claims to nothingness is the exact approach the Supreme Court cautioned may "swallow all of patent law" because "[a]t some level, 'all inventions . . . embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.'" *Alice*, 134 S. Ct. at 2354 (quoting *Mayo*, 132 S. Ct. at 1293).

Defendants' generalizations gloss over the context for the "superimposing" and "deforming" steps, applying generic interpretations that fail to acknowledge the specialized algorithms or homology mapping required by the claims. (*E.g.*, Br. at 1-2, 5-6, 8, 13, 15, 17.) For example, Defendants wrongly represent to the Court (at 1-2) that the claims cover any physician who "tinkers" with a shape on a computer screen or simply "envisioning the shape of an implant." Divorcing the claim terms from any context provided by the claims or the specification, Defendants (at 6-8, 13) incorrectly equate the "deforming" step with "adjusting an image of a normal piece of tissue or bone to fit in a hole," or "artistically" molding a physical implant. Defendants also make other nonsensical arguments, such as the claimed methods covering the human "mental process of looking at an image of a bone that is missing a piece" and visualizing the necessary implant to fill in the missing piece. (*E.g.*, Br. at 5, 13.)

The claim language, however, requires that a computer perform the claimed steps. Indeed, the claims are directed to computer-based techniques that cannot (and never could) be performed by humans. For example, a human cannot determine a precise match between the curved surfaces and/or anatomical landmarks of a normative 3-dimensional template and a 3-dimensional image of patient data. Likewise, a human cannot deform a normative template in three dimensions to determine the best possible match for the existing anatomy while maintaining homology. These "superimposing" and "deforming" steps are not a conventional human practice merely transferred to computers. Defendants' view—that a physician could "envision[] the desired shape of the implant"—makes little sense and represents the failed approach that first caused the medical field to use computer-based methods to design devices and that later led to the Osteoplastics inventions. (*See* Br. at 2, 5, 13.)

Accordingly, Defendants' allegations of abstract idea based on human activity fails. *Contentguard Holdings, Inc. v. Amazon.com, Inc.*, No. 13-01112, 2015 WL 5853984, at *4-5 (E.D. Tex. Oct. 5, 2015) (finding a claim could not be practiced by a human because a library could not prevent unauthorized use, it could only punish a patron after the fact); *cf. Execware, LLC v. BJ's Wholesale Club, Inc.*, No. 14-233-LPS, 2015 WL 4275314, at *14 (D. Del. July 15, 2015) (adopted in part, rejected in part) (finding Defendants' pen and paper analogy flawed because it "did not accomplish the goals of the invention or produce its actual effect"); *California Inst. of Tech. v. Hughes Commc'ns Inc.*, 59 F. Supp. 3d 974, 994-95 (C.D. Cal. 2014) (noting that many inventions can be theorized with a human, pencil, and paper, "but pencil and paper can rarely produce the actual effect of the invention").

Defendants' characterization of the claims as merely "collecting, displaying, and manipulating data" is also incorrect. (*E.g.*, Br. at 10, 16). Here again, Defendants sweep over

the claim language, the specific techniques claimed to design a medical device that fits the patient precisely, and the improvements over existing computer-based design methods. Defendants' incorrect characterization of the claims cannot satisfy their burden on the first *Alice* step. *See*, *e.g.*, *MAZ Encryption*, 2016 U.S. Dist. LEXIS 134000, at *18 (rejecting arguments for "oversimplif[ying] key inventive concepts" and "downplay[ing] an invention's benefits," and admonishing the court "must look to the claims as an ordered combination, ***without ignoring the requirements of the individual steps***" (internal citations omitted)). At a minimum, Defendants' argument creates a factual dispute regarding what is routine and conventional that cannot be resolved on a motion to dismiss. *Berkheimer*, 881 F.3d at 1369-70; *Aatrix Software Inc. v. Green Shades Software Inc.*, 882 F.3d 1121, 1125-26 (Fed. Cir. 2018).

C. The Osteoplastics Claims Are Similar to Those Found Eligible By the Federal Circuit and the Court.

The Federal Circuit has repeatedly confirmed that software can make patent-eligible improvements to computer technology, and that related claims are eligible as long as they are directed to non-abstract improvements to the functionality of a computer or network platform. *See Customedia Techs., LLC v. Dish Network Corp.*, 951 F.3d 1359, 1364 (Fed. Cir. 2020) (collecting cases). The claims of the Osteoplastics patents are similar to other claims that the Federal Circuit found patent-eligible under step one of the *Alice* framework.

For example, in *CardioNet, LLC v. InfoBionic, Inc.*, the claims covered a device for "detecting and reporting the presence of atrial fibrillation or atrial flutter in a patient." 955 F.3d 1358, 1363-65 (Fed. Cir. 2020). The Federal Circuit found no suggestion in the patent that doctors were "previously employing" the claimed techniques. *Id.* at 1370. Nor did the record "suggest[] that the claims merely computerize pre-existing techniques for diagnosing atrial fibrillation and atrial flutter." *Id.* "[T]he written description of the [patent-at-issue] confirms

that the asserted claims are directed to a specific technological improvement—an improved medical device that achieves speedier, more accurate, and clinically significant detection of two specific medical conditions out of a host of possible heart conditions." *Id.*

Similarly, in *SRI International, Inc. v. Cisco Systems, Inc.*, the Federal Circuit found claims patent eligible that improved computer functionality by "providing a network defense system that monitors network traffic in real-time to automatically detect large-scale attacks." 930 F.3d 1295, 1303 (Fed. Cir. 2019). The claims required "network monitors in the enterprise network" to detect suspicious activity, generate reports of the activity, and automatically receive and integrate those reports. *Id.* at 1301. "[T]he representative claim improve[d] the technical functioning of the computer and computer networks by reciting a specific technique for improving computer network security," and was not directed to an abstract idea. *Id.* at 1304.

In *Finjan, Inc. v. Blue Coat System, Inc.*, the claims recited a method of providing computer security by generating a "security profile" that identifies suspicious code that performs "potentially hostile operations." 879 F.3d 1299, 1303-04 (Fed. Cir. 2018). Unlike traditional systems that "simply look[ed] for the presence of known viruses," the claimed method could identify "potentially dangerous or unwanted operations." *Id.* at 1304. The claimed method was directed to a "non-abstract improvement" over the prior art because it employed "a new kind of file that enable[d] a computer security system to do things it could not do before." *Id.* at 1305.

In *McRO, Inc. v. Bandai Namco Games Am. Inc.*, the claims covered a "method for automatically animating lip synchronization and facial expression of three-dimensional characters." 837 F.3d 1299, 1307 (Fed. Cir. 2016). The Federal Circuit held that the claims were directed to "a specific asserted improvement in computer animation, i.e., the automatic use of rules of a particular type," which was confirmed by the patent's written description. *Id.* at

1313-14. The court rejected the argument that the claims "simply use a computer as a tool to automate conventional activity" because there was no evidence in the record that "the process previously used by animators [wa]s the same as the process required by the claims." *Id.* at 1314.

And in *Enfish*, the Federal Circuit held that claims regarding a self-referential table for a computer database were not abstract, even though the table ran on a general-purpose computer, because the claims improved the storage and retrieval of data and, thus, were "directed to a specific implementation of a solution to a problem." *Enfish*, 822 F.3d at 1337-39. The court found the "plain focus of the claims is on an improvement to computer functionality itself, not on economic or other tasks for which a computer is used in its ordinary capacity." *Id.* at 1336.

The Federal Circuit has also found claims that improve computer functionality patent eligible in many other cases. *E.g.*, *Data Engine Techs. LLC v. Google LLC*, 906 F.3d 999, 1007–08 (Fed. Cir. 2018) (finding claims patent eligible that recited a "specific method for navigating through three-dimensional electronic spreadsheets" because they improved the computer's functionality); *Core Wireless Licensing S.A.R.L. v. LG Electronics, Inc.*, 880 F.3d 1356, 1359–63 (Fed. Cir. 2018) (finding claims directed to an improved user interface that enabled users to more quickly access stored data and programs in small-screen electronics patent eligible because they "improve[d] the efficiency of using the electronic device by bringing together a limited list of common functions and commonly accessed stored data, which can be accessed directly from the main menu"); *Thales Visionix Inc. v. United States*, 850 F.3d 1343, 1348-49 (Fed. Cir. 2017) (finding disclosing an inertial tracking system for tracking the motion of an object relative to a moving time reference were not directed to an abstract idea because the claims specified "a particular method of using the raw data from the sensors" more accurately and with fewer complications than conventional methods); *Visual Memory LLC v. NVIDIA Corp.*, 867 F.3d

1253, 1257-60 (Fed. Cir. 2017) (finding the claims were "directed to an improved computer memory system, not to the abstract idea of categorical data storage").

Like the claims that deemed patent eligible by the Federal Circuit, Osteoplastics claims address and improve upon pre-existing computer-based medical device design methods. The patents' Background Sections discuss "methods of fabricating prosthetic implants" and the goal of obtaining a custom medical device that precisely matches the patient's anatomy. (4:29-53.) Nowhere do the patents state a desire to replicate human activity or mental processes. Indeed, humans could not performed the claimed method. Nor would there be an advantage in replicating a human design process that produced undesirable devices. Rather the invention seeks to solve shortcomings that arose with the advent of the computerized design of custom medical devices. The claimed solution recites specific, discrete computer-based steps to design and fabricate a custom medical device with the most accurate fit for the patient anatomy.

Defendants' reliance on *Align* is misplaced. *See Align Tech., Inc. v. 3Shape A/S*, 339 F. Supp. 3d 435, 453 (D. Del. 2018). The Osteoplastics claims go far beyond the "abstract concept of modifying a finish line of a dental prosthesis" that the *Align* court found patent ineligible. *Id.* at 451-452. Instead, the claims are similar to those the *Align* court affirmed as patentable because they covered a specific improvement that solved the specific problem of preventing degradation of a 3D model of a tooth. *Id.* at 450. Defendants argue (at 12) that the patentable techniques at issue in the *Align* case were "not a technique transferrable to the manual world." But this is also true of the "superimposing" and "deforming" techniques here that can only be performed using specialized computer algorithms. Moreover, Defendants argue (at 12) that techniques found patentable "allegedly used virtual objects to create a new type of physical implement [i.e. a dental template] . . . ." *Align*, 339 F. Supp. 3d at 456-457. Again, the

Osteoplastics claims provide a similar inventive concept that uses virtual objects (i.e., normative templates and 3D images of patient anatomy) to create a new type of physical implement (i.e. improved medical devices based on anatomical landmarks and maintaining homology).

D. Defendants' Motion Raises Material Claim Construction and Factual Disputes That Cannot Be Resolved Under Rule 12(b)(6).

The Court "may decline to rule on a Rule 12 motion before engaging in claim construction, or may deny the motion if it appears there are potential constructions of key claim terms that, if adopted, would render the claims subject matter eligible." *Versata Software, Inc. v. NetBrain Techs., Inc.*, C.A. No. 13-676-LPS-CJB, 2015 WL 5768938, at *2 (D. Del. Sept. 30, 2015) (internal citations omitted). Claim construction is necessary in a § 101 analysis because "the determination of patent eligibility requires a full understanding of the basic character of the claimed subject matter." *Bancorp Servs., L.L.C. v. Sun Life Assurance Co. of Canada (U.S.)*, 687 F.3d 1266, 1273-74 (Fed. Cir. 2012).

Defendants do not propose claim constructions for any terms. Instead, they argue incorrectly that "superimposing" and "deforming" a "template" in claim 1 of the '206 patent are "generic steps . . . with no concrete result other than data that may be used 'to determine the 3-dimensional shape of the medical device.'" (*E.g.*, Br. at 9.) While it is unlikely Defendants will advocate this view when addressing claim construction and infringement later in the case, their current position reveals a material dispute. As explained previously, the "superimposing" and "deforming" terms are not generic and describe specific techniques that improved over existing computer-based methods. Osteoplastics submitted claim construction briefing and evidence on these terms in the Colorado litigation, which Defendants never address. The proper construction of these terms undercuts Defendants' conclusory, attorney argument that the claims are generic, do not produce a concrete result, and set forth abstract ideas.

Additionally, "[w]hether something is well-understood, routine, and conventional to a skilled artisan at the time of the patent is a factual determination." *Berkheimer*, 881 F.3d at 1369-70. The Federal Circuit has confirmed that determining what is "routine and conventional"—which Defendants again allege based on attorney argument that is contradicted by the evidence of record—cannot be decided on a motions to dismiss or summary judgment. *Berkheimer*, 881 F.3d at 1369-70; *Aatrix Software*, 882 F.3d at 1125-26. Because factual disputes exist over the conventionality of Osteoplastics' invention, the disputes must be resolved in favor of Osteoplastics and Defendants' motion should be denied. *Aatrix Software*, 882 F.3d at 1125 (patent eligibility may only be resolved under Rule 12(b)(6) when "no factual allegations that, taken as true, prevent resolving the eligibility question as a matter of law").

E. Defendants' Motion Focuses On One Claim and Fails to Address the Validity of Other Claims in the Seven Osteoplastics Patents.

"Defendants bear the burden to demonstrate that their asserted Section 101 defense is well taken as to each claim." *Versata Software*, 2015 WL 5768938, at *4. Where a motion challenges the patent eligibility of multiple patent claims based on the analysis of a single claim, that single claim must be representative of all challenged claims. *See Cronos Techs., LLC v. Expedia, Inc.*, C.A. No. 13-1538-LPS, 2015 WL 5234040, at *2 (D. Del. Sept. 8, 2015). Defendants must show the analyzed claim is representative by "articulat[ing] why each of" the challenged claims "relates to the same abstract idea purportedly embodied by" the analyzed claim and "explain[ing] why each of" the challenged claims "fails to include an inventive concept." *Id.* at *3. Where "Defendants focus[] the lion's share of their attention on particular claims for each patent" and give "negligible attention to the remainder of the claims," the motion should be denied as to the unanalyzed claims. *Versata Software*, 2015 WL 5768938, at *4.

As an initial matter, Defendants are incorrect (at 16) that the complaints only assert "claim 1 of each of the Asserted Patents." The passage identified by Defendants actually states that they infringe "one or more claims of each of the Asserted Patents" and further states the seven charted claims are examples. (*E.g.*, D.I. 9 at ¶ 31.[6]) Defendants' infringement encompasses many other claims, which Osteoplastics will identify in its infringement contentions at the appropriate time. In any event, Defendants focus their analysis on claim 1 of the '206 patent, but offer only conclusory assertions that this claim represents every other claim in the seven Osteoplastics patents. (Br. at 4-5, 16-18.) This falls well short of satisfying the established standard. *See Cronos Techs.*, 2015 WL 5234040, at *2.

Moreover, the other claims include significant differences that prevent any one claim from being representative. *See Berkheimer*, 881 F.3d at 1365-66. For example, the "anatomical landmarks" recited in the claims of the '302, '191, and '920 patents further contradict Defendants' characterization that the "superimposing" and "deforming" steps are abstract concepts. These "landmarks" are used in embodiments of the algorithms that perform the "superimposing" and "deforming" steps that appear in the claims and specification. Several dependent claims also require the image of the patient anatomy consist of "image slices," "scan lines," or "voxels." (*E.g.*, '557 claims 2-3, '920 claims 8-10, '206 claims 2-3, '302 claims 2-3, '191 claims 3-5, '617 claims 3-4, '756 claim 3.) These distinct types of image data require different processing to render a 3D representation of the patient anatomy. For example, image slices are 2D data while voxels are 3D data, so unlike with voxels, the computer must convert

[6] Unless otherwise indicated, for the Court's convenience all docket citations are specific to the -406 action against the DePuy Defendants. The Amended Complaints in the -405 action (naming Conformis) and the -407 action (naming Zimmer Biomet Defendants) are docketed as D.I. 7 and D.I. 8, respectively.

image slices into 3D data before it can create a 3D representation. Other dependent claims require determining the shape of the medical device as "a function of the shapes of the defective portion and the template," "establishing correspondence between the mapped highly curved portions" of the patient anatomy and the template, or "registering data from the mapped external surface of the non-defective portion of the target tissue to normative data for the target tissue prior to superimposing the template." ('920 claims 4 and 6-7, '191 claims 2, 11 and 13, '617 claim 2.) These claims require specific relationships between the shapes of the patient anatomy, template, and medical device that further limit the methods in the independent claims. Other dependent claims require fabricating a medical device using a "3D rendering device," which is specific equipment that distinguishes over what Defendants allege (at 18) to be generic "fabrication" requirements. ('920 claim 15, '191 claim 8.) Defendants cannot carry their burden with respect the unanalyzed claims of the '206 patent and its § 101 challenge for those claims can be denied. *See Versata Software*, 2015 WL 5768938, at *4.

F. The Osteoplastics Patents Claim an Inventive Concept.

Even if Defendants could demonstrate an abstract idea under the first *Alice* step, which they cannot, the Osteoplastics patents claim an inventive concept. The Federal Circuit has consistently held that an "inventive concept" exists when a claim "recite[s] a specific, discrete implementation of the abstract idea" where the "particular arrangement of elements is a technical improvement over [the] prior art." *BASCOM Global*, 827 F.3d at 1350. The claims here recite specific techniques for designing custom medical devices that require, among other things, superimposing and deforming. These are specific computer techniques that are narrowly-tailored to achieve a medical device shape that fits the patient's anatomy.

Defendants ignore the inventive concepts and improvements captured by the Osteoplastics claims, dismissing references to "superimposing" a normative template to a patient

image and "deforming" the template to fit the patient anatomy as "[m]erely requiring the selection and manipulation of information." Defendants (at 13-16) cannot negate the vast improvement over the prior art by summarizing the claims in a way that reads out the benefits of the "superimposing" and "deforming" steps. The § 101 inquiry does not occur in a vacuum. The improvements over existing computer-based methods discussed in the specification and identified throughout the prosecution history demonstrate that the claims set forth a specific implementation and do not merely capture an abstract idea. For the reasons explained previously, the combination of claim elements amounts to something significantly more than merely determining the shape of a medical device by tinkering with a computer.

Where previous design methods had created medical devices that caused lengthy surgeries and post-operative complications, the claims represent a significant improvement of both the quality of custom medical devices and improved surgical outcomes. Defendants' "surgical mesh" example actually illustrates the claimed inventive concept. (*See* Br. at 15.) Unlike the Osteoplastics claims, the physician in this prior art method "artistically" molds surgical mesh to a 3D anatomical model of the patient anatomy. (*Id.*) In doing so, the physician guesses as to the shape of the surgical mesh, based on a physical/mental comparison between the defective portion of the anatomy and the mirror-image anatomical model. The method requires a physician to make free-hand adjustments to the mesh, guessing how to bend and shape the mesh to correct for any inconsistencies between the model and the patient. In contrast, the claimed computerized methods determine the precise anatomical contours for a medical device, using techniques that vastly improved on this physician-based method and other attempts to design medical devices with a computer. *Cf. Diamond v. Diehr*, 450 U.S. 175 (1981) (finding patent eligible a combination of claim elements used to eliminate the guesswork with existing,

inaccurate industrial process for curing synthetic rubber). Defendants' other prior art examples fare no better, as the "aligning" and "smoothing" steps described in these references fail to disclose the particular inventive steps discussed at length previously. (Br. at 14-15, *see also* Br. at 7-8.) They actually confirm that Osteoplastics' claims are narrowly-tailored and provide a specific improvement over prior art computer-based methods.

G. The Osteoplastics Claims Do Not Preempt all Methods of Computer-Based Medical Device Design and Fabrication.

The concern that drives the exclusion of abstract ideas as patentable subject matter is one of preemption. *Alice*, 134 S. Ct. at 2354, 2358 ("the pre-emption concern . . . undergirds our § 101 jurisprudence"); *Bilski v. Kappos*, 561 U.S. 593, 611-12 (2010) (patenting an abstract idea "would pre-empt the use of this approach in all fields, and would effectively grant a monopoly over an abstract idea"). The second *Alice* step focuses on whether the claims "disproportionately tie up the use of the underlying ideas." *Cronos*, 2015 WL 5234040, at *2 n.3 (quoting *Alice*).

While the claims may offer the best solution available for determining the 3D shape of a custom medical device, they came after other parties spent years developing computer-based methods for designing custom devices and leave other parties ample room in the future to practice and innovate in the field. *See Intellectual Ventures I LLC v. Mfrs. & Traders Trust Co*, 76 F. Supp. 3d 536, 548 (D. Del. 2014) (determining the claims "do not preempt all applications of providing customized web pages as they recite a specific method of customizing web pages"). In fact, Defendants contradict their own argument that the claims "monopolize the basic process of . . . envisioning the shape of an implant" by describing several prior art approaches that were discussed in the specification and file histories of the Osteoplastics patents. (*E.g.*, Br. at 5-8, 14-15.) Moreover, there can be no dispute that the claims do not cover methods where a medical device is designed on a computer "from scratch," i.e. without the use of a template. Likewise,

methods that position device shapes over patient images but do not "superimpose" or "deform" those shapes, while inferior, also fall outside the scope of claim 1 of the '206 patent. This includes the prior art methods Defendants describe that "smooth" or "align" a shape without "superimposing" or "deforming." (*E.g.* Br. at 14-15.) These tangible, concrete alternatives demonstrate that the Osteoplastics claims do not create any concerns of preemption.

VII. THE AMENDED COMPLAINTS IN ALL THREE ACTIONS PROPERLY STATE A CLAIM FOR INFRINGEMENT UNDER § 271(G).

The allegations and attached claim charts in all three of Osteoplastics' Amended Complaints are sufficient to state a claim for infringement under § 271(g). *E.g.*, *Bayer AG v. Housey Pharm., Inc.*, 340 F.3d 1367, 1376 (Fed. Cir. 2003). In *Bayer*, the Federal Circuit explained that infringement under § 271(g) reaches methods "used directly in the manufacture of the product." *Id.* at 1378. Osteoplastics' infringement allegations identify the methods in the asserted patents used in the manufacture of Defendants' infringing products. For example, the Amended Complaint for the DePuy Defendants identifies the ProPlan and TruMatch products they manufacture using the claimed methods. (*E.g.*, D.I. 9 at ¶ 30-31; D.I. 9-8.)

Defendants are wrong (at 18-20) that the claims infringed under § 271(g) are used as "a predicate process to identify the product to be manufactured." Defendants use these methods directly in the manufacturing process for the infringing products. *Bayer*, 340 F.3d at 1378. Moreover, Defendants admit (at 20) that claim 1 of the '191 patent requires the fabrication of an implant and do not explain (or even address) why this claim—or any of the other numerous claims disclosing the fabrication and manufacture of medical devices, such as '920 claim 15 or '617 claim 8—does not satisfy § 271(g) under Federal Circuit precedent.

Several courts have also held that digital creations can constitute products within the meaning of § 271(g). *E.g.*, *CNET Networks, Inc. v. Etilize, Inc.*, 528 F. Supp. 2d 985 (N.D. Cal.

2007); *Ormco Corp. v. Align Tech., Inc.*, 609 F. Supp. 2d 1057 (C.D. Cal. 2009). In *CNET Networks*, the patent claimed methods and systems for automatically creating an electronic catalog of product information gathered from various internet websites. The digital catalogue was deemed a product under § 271(g) because the infringing method was used to create a product (the catalogue) that was subsequently imported into the United States. The court distinguished *Bayer* because it dealt with an infringing process for the service of transmitting information to recipients in the United States. *Id.* Likewise, in *Ormco*, the court found a three-dimensional digital representation of teeth transmitted to recipients was a "'creation' produced by 'practicing each step' of patented process." 609 F. Supp. 3d 1057 (C.D. Cal. 2009).

VIII. THE DEPUY AMENDED COMPLAINT PROPERLY STATES A CLAIM FOR INFRINGEMENT UNDER § 271(a) AND WILLFUL INFRINGEMENT.

The purpose of Rule 8's notice pleading standard is "to give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Twombly*, 550 U.S. at 555 (internal quotation marks and citation omitted). Osteoplastics' Amended Complaint against the DePuy Defendants supports a reasonable inference that they are liable for the patent infringement Osteoplastics alleges and complies with Rule 8 (which is also true for the other Defendant groups that refused to join DePuy's motion on this ground).

Defendants incorrectly argue (at 20-22) that the Amended Complaint fails to specify which Defendant performs the asserted method claims. At the pleading stage, Osteoplastics need only place Defendants on fair notice of the activity accused of infringement. *Lifetime Indus., Inc. v. Trim-Lok, Inc.*, 869 F.3d 1372, 1379 (Fed. Cir. 2017); *see also Twombly*, 550 U.S. at 555. The Amended Complaint satisfies this requirement by alleging that "Defendants" are and have been directly infringing the Asserted Patents. The Complaint defines "Defendants" to include each of DePuy Synthes, Inc., DePuy Synthes Products, Inc., Medical Device Business Services,

Inc., and Synthes, Inc. (*See*, *e.g.*, D.I. 9 ¶ 30; D.I. 9-8.) Thus, the Complaint alleges that *each* of the entities perform each step of the method claims. The Complaint includes infringement claim charts that explain how Defendants perform each step of the method claims when they design and manufacture medical devices, such as their ProPlan and TruMatch products. (D.I. 9-8.) This includes images from Defendants' website and product information that further support Osteoplastics' "plausible claims of direct infringement of the asserted method claims." *Valinge Innovation AB v. Halstead New England Corp.*, C.A. No. 16-1082-LPS-CJB, 2017 WL 5196379, at *2 (D. Del. Nov. 9, 2017). Defendants' demand for more detail is unwarranted at this stage.

Defendants' concern (at 22) that the Amended Complaint does not allege sufficient detail as to how each Defendant performs each of the claimed steps is unfounded and "ask[s] for too much." *Lifetime Indus.*, 869 F.3d at 1379. "There is no requirement for [Osteoplastics] to 'prove its case at the pleading stage.'" *Id*. (quoting *In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1339 (Fed. Cir. 2012)). Federal Circuit "precedent requires only that a complaint place the alleged infringer 'on notice of what activity . . . is being accused of infringement.'" *Id*. (quoting *K-Tech Telecomms., Inc. v. Time Warner Cable, Inc.*, 714 F.3d 1277, 1284 (Fed. Cir. 2013)) (ellipsis in original). Thus, the inquiry is simply whether the plaintiff "has provided sufficient information to allow the court to determine plausibility and to allow the named defendant to respond to the complaint." *DermaFocus LLC v. Ulthera, Inc.*, 201 F. Supp. 3d 465, 470 (D. Del. 2016) (rejecting argument that direct infringement allegations were insufficient for not alleging "how all of the claimed method steps are performed").

Defendants are also wrong that Osteoplastics alleges a third party (Materialise) performs steps of the claimed method. The Amended Complaint and claim charts specifically allege that each of the Defendants uses Materialise software (or software that is materially similar) to

perform each of the steps of the claimed methods. (D.I. 9 at ¶ 30; D.I. 9-8.) Osteoplastics never states that Materialise itself performed the steps of the claimed method. Instead, Osteoplastics cites evidence relevant to Defendants' products and their use of Materialise software (including Mimics) to perform the claimed methods. (*E.g.*, D.I. 9-8 at 2-5.)

The allegations in the Amended Complaints are consistent with those deemed sufficient by the Court. *See*, *e.g.*, Transcript of Oral Argument Hearing dated Dec. 5, 2017, *Hanesbrands, Inc. v. Jacques Moret, Inc.*, C.A. No. 17-595-LPS (Stark, C.J.) (hereinafter "*Hanesbrands* Transcript Order") at 30:11-31:22 (holding direct infringement adequately pleaded where complaint stated exemplary claims with respect to exemplary products). No greater detail is required. Defendants' motion effectively seeks infringement contentions at the pleading stage, which is inappropriate, particularly in light of the discovery standard governing disclosure of infringement contentions. *See Koninklijke Philips N.V. v. ASUSTeK Comput. Inc.*, C.A. No. 15-1125-GMS, 2016 U.S. Dist. LEXIS 147169, at *13-14 (D. Del. Oct. 25, 2016) (emphasizing the local rules regarding infringement contentions and finding direct infringement adequately alleged where the complaint provided details of at least one infringed claim and examples of one product the defendant manufactures or sells performing the identified functions); *Hanesbrand* Transcript Order at 31:11-17 ("Essentially in my view, defendant asks for something analogous or akin to infringement contentions to be contained in the complaint . . . . And I'm not persuaded that the Supreme Court or the Federal Circuit or any other authority requires that that be done . . . .").

Moreover, given the pre-suit communications between the parties, Defendants cannot complain about the sufficiency of Osteoplastics' infringement allegations. In its months-long discussions with Defendants, Osteoplastics specifically requested information relating to Defendants' alleged infringing activities. (D.I. 1-9.) Defendants refused, which forced

Osteoplastics to file this case alleging infringement on information and belief based on publicly-available information and relying on the Federal Circuit's *Hoffman-La Roche* line of cases. (*E.g.*, D.I. 9 at ¶ 30; D.I. 9-8.) Defendants' allegations (at 20-22) that the Amended Complaint is deficient for lack of specificity is contrary to well-settled law. *Hoffmann-La Roche Inc. v. Invamed Inc.,* 213 F.3d 1359, 1361-62 (Fed. Cir. 2000).

Osteoplastics' willful infringement claims are also sufficient because they allege pre-suit knowledge and infringement of at least three asserted patents. Nothing more is required. Indeed, "[a]t the pleading stage, it is not necessary to show that the case is egregious." *Bio-Rad Labs. Inc. v. Thermo Fisher Sci. Inc.*, 267 F. Supp. 3d 500, 501 (D. Del. 2017). Defendants are wrong (at 23-24) that Plaintiffs did not sufficiently allege Defendants' knowledge of infringement. The facts alleged by Osteoplastics in the Amended Complaint give rise to a plausible inference of pre-suit knowledge, which included a 2017 letter to Defendants with detailed infringement claim charts for the '557, '920, and '206 patents. (D.I. 1-9, D.I. 9 at ¶¶ 18, 32-35.) The letter also asked Defendants to provide information on their accused methods and any position they might have on infringement—information that Defendants refused to provide. (*Id.*) These facts are sufficient to state a claim for willful infringement. *See Rhodes Pharm. L.P. v. Indivior, Inc.*, No. 16-1308, 2018 U.S. Dist. LEXIS 2622, at *24-25 (D. Del. Jan. 8, 2018); *Hanesbrand* Transcript Order at 32:3-9 ("With respect to willful infringement, I think that again the plaintiff has adequately for this stage of the case stated a plausible allegation of willful infringement, particularly that after the defendant was on notice of the alleged infringement, they have continued to sell allegedly infringing products. I don't think that more needs to be done.").

Defendants' request (at 23) for the dismissal of the willfulness claim against Synthes, Inc. and MDBS are incorrect. Osteoplastics' 2017 letter was addressed to the DePuy Synthes group

of companies, which includes MDBS (formerly known as DePuy Orthopaedics, Inc.), as well as Synthes, Inc. (along with the other named Defendants in this case). (D.I. 1-9.) The lawyer for the group of companies (Lynn Malinoski) responded to Osteoplastics' allegations. (D.I. 1-10.) Because Defendants operate as a group of companies and were accused of infringement as a group of companies, Osteoplastics' pre-suit correspondence provides sufficient facts giving rise to a plausible inference that each of the named Defendants had pre-suit knowledge of its infringement of the identified patents.

IX. CONCLUSION

For the reasons set forth above, Osteoplastics' patents claim eligible subject matter and its Amended Complaints are sufficient under Rule 8, as well as Supreme Court and Federal Circuit precedent. Osteoplastics respectfully requests that Defendants' motion to dismiss be denied. To the extent, however, that the Court finds any deficiency in Osteoplastics' Amended Complaints, Osteoplastics respectfully requests that it be granted leave to file an amended complaint to address such deficiency. Fed. R. Civ. P. 15(a)(2); *see also Foman v. Davis*, 371 U.S. 178, 182 (1962); *Free Speech Coal., Inc. v. Att'y Gen. of U.S.*, 677 F. 3d 519, 545 (3d Cir. 2012); *Aatrix Software,* 882 F.3d at 1125-26.

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